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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,505	01/16/2002	William J. Roberts	1400-004	8577

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EXAMINER

QAZI, SABIHA NAIM

ART UNIT PAPER NUMBER

1616

DATE MAILED: 09/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/053,505

Applicant(s)

ROBERTS, WILLIAM J.

Examiner

Sabiha Naim Qazi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 16 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) 11-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 11-58 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☒ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 1616

First Office Action on Merits

DETAILED ACTION

Claims 1-58 are pending.

Claims 1-10 are examined; others are withdrawn from consideration as non-elected invention.

Election/Restrictions

Claims 1-58 are generic to a plurality of disclosed patent ably distinct species comprising multiple species drawn to androstane and estr-4-ene derivatives and their methods of use. A telephone call was made to Attorney Stephen T. Sullivan on 8/28/2002 to request an oral election to the above restriction requirement, but did not result in an election being made.

Mr. Sullivan called on 9/6/2002 and proposed a restriction by dividing the invention into four groups.

Group I, claims 1-10

Group II, claims 11-20.

Group III, claims 21-39.

Group IV, claims 40-58.

In order to advance the prosecution proposed the Examiner accepted groups. Applicants have elected Group I and will file divisional for other groups.

Applicant in replying to this Office action must make affirmation of this election. Claims 21-58 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for any other Group, restriction for examination purposes as indicated is proper.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

1. Claims 1-10 rejected under 35 U.S.C. 102(b) as being anticipated by Arnold (US Patent 5,880,117) and Mattern et al. (US 5,578,588). See lines 1-55, col. 2 and claims in US '588. The reference discloses a drug containing at least one testosterone precursor, for increasing the level of testosterone in the human body, See lines 14-63, Figures and claims in US' 117. The reference discloses 4-androstenediol for increasing concentration of parent androgen, testosterone.
2. Claim 4 and 6 rejected under 35 U.S.C. 102(b) based upon a public use or sale of the invention. See compound 4-androstenediol ethyl carbonate (Monoester and diester) in the certification of analysis provided by Applicant. TAIZHOU XINGYE CHEMICAL FACTORY sells the product. Manufacturing date 12/29/2001.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Art Unit: 1616

1. Claims 1-10 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Following reasons apply.

The term "comprising" cited in claims is inclusive and fails to exclude unrecited steps. The use of the term comprising to introduce claimed structure means that the ingredients covered by these claims may involve more elements than those positively recited. *Ex parte Gottzein et al.*, 168 USPQ 176 (PTO Bd. App. 1969). Comprising leaves the claim open for inclusion of unspecified ingredients even in major amounts. *Ex parte Davis et al.*, 80 USPQ 448 (PTO Bd. App. 1948).

The term "including" in claim 1 may include elements other than those recited in claims. See *Ex parte Russell*, 153 USPQ 752 (PTO Bd. App. 1966). Deletion of this term is suggested.

It is unclear what is intended by "parent androgen comprising 4 and a 17 position" in claim 1.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-, 2, 5-7, 9 and 10 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for androst-4-ene-3, 17beta-diol 17 beta alkyl carbonates, does not reasonably provide enablement for every compound having 4 and 17 position in the structure. The specification does not enable any person skilled

Art Unit: 1616

in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Since the nature of the method is so unpredictable, and since there is a lack of guidance present in the specification, the skilled artisan would have to undertake undue experimentation to practice the claimed invention commensurate with the scope of the claims. The skilled artisan, seeking lead compounds for pharmaceutical discovery, would be at a loss as to where to begin such discovery in the absence of such disclosure.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-10 rejected under 35 U.S.C. 103(a) as being unpatentable over Arnold (US Patent 5,880,117) and Mattern et al. (US 5,578,588). See the entire documents especially lines 1-55, col. 2 and claims in US '588. The reference discloses a drug

Art Unit: 1616

containing at least one testosterone precursor, for increasing the level of testosterone in the human body. See especially lines 14-63, Figures and claims in US' 117. The reference discloses 4-androstenediol for increasing concentration of parent androgen, testosterone that embraces Applicant's claimed invention.

1. Determining the scope and contents of the prior art.

Prior art cited above teach the use of a drug, which is a precursor of testosterone to increase its level in human body.

2. Ascertaining the differences between the prior art and the claims at issue.

Instant claims differ from the prior art in claiming a broader scope by claiming "androgen" where as prior art teach testosterone precursors. Testosterone is an androgen.

3. Resolving the level of ordinary skill in the pertinent art.

Since prior art teaches the increase in testosterone level in human body by using its precursor it would have been obvious to prepare addition drugs or prodrugs using the same teaching to use the precursor of the androgen which is desired to increase the level of androgen as testosterone precursor liberates testosterone and increases its level in human body.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

It would have been obvious at the time of invention to be motivated to prepare additional testosterone or any other androgens by using their precursors to increase the level of

Art Unit: 1616

testosterone or any other androgen in human body when needed because prior art teach such drugs or prodrugs.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Naim Qazi whose telephone number is 703-305-3910. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

September 7, 2002



SABIHA QAZI, PH.D
PRIMARY EXAMINER